



Heritage Information Systems, Inc.



## Clinical Edit Criteria Proposal

Drug/Drug Class: **Fluconazole (Diflucan) Clinical Edit**

Prepared for: **Missouri Medicaid**  
Prepared by: **Heritage Information Systems, Inc.**

☒ **New Criteria**

☐ **Revision of Existing Criteria**

### Executive Summary

**Purpose:** Reduce the potential for overutilization of oral Fluconazole 150mg tablet in treating vaginal candidiasis.

**Why was this Issue Selected:** Diflucan oral 150mg Tablet is specifically formulated for one-time administration for vaginal candidiasis.

Program-specific information:	Drug	Claims	Expense
	• Diflucan 150mg Tablet	36,995 03/02-02/03	\$681,750

**Setting & Population:** Prescribed as single oral dose for vaginal candidiasis therapy.

**Type of Criteria:**

<input type="checkbox"/> <b>Increased risk of ADE</b>	<input type="checkbox"/> <b>Non-Preferred Agent</b>
<input checked="" type="checkbox"/> <b>Appropriate Indications</b>	<input type="checkbox"/> <b>Other</b>

**Data Sources:**

<input checked="" type="checkbox"/> <b>Only administrative databases</b>	<input type="checkbox"/> <b>Databases + Prescriber-supplied</b>
--------------------------------------------------------------------------	-----------------------------------------------------------------

### Purpose of PA Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended clinical edit programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber

behavior and guide appropriate medication usage. Clinical edit criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

## Why Has This Clinical Issue Been Selected For Review?

Vulvovaginal candidiasis (VCC) is a fungal infection typically caused by *Candida albicans*. While 10-20% of women are colonized with *C. albicans*, treatment is only recommended in those patients with both signs (e.g., positive KOH or culture) and symptoms (e.g., pruritus, erythema, white discharge) of *Candida* vaginitis.<sup>1</sup> Seventy-five percent of all women will experience at least one case of symptomatic vaginal candidiasis and half of those will experience a second episode. Additionally, 10-20% will have complicated VCC and 5% will experience recurrent VCC (greater than 4 episodes per year).<sup>2,3</sup>

In the Spring of 2002, the Centers for Disease Control and Prevention (CDC) published the Sexually Transmitted Disease Treatment Guidelines for 2002.<sup>1</sup> This document includes recommendations for the diagnosis, treatment and follow up for patients with VCC. For uncomplicated VCC, short-term topical or oral azole antifungals are the considered first line of treatment due to their cure rates of 80-90%. These patients should be instructed to return for follow up when symptoms persist or recur within two months of the initial episode. Additionally, patients with complicated VCC (e.g., recurrent or recurrent VVC or women with diabetes, immunosuppressed or pregnant) may require either longer topical (7-14 days) or oral (e.g., 150mg fluconazole repeated 3 days after initial dose) therapy.

While Diflucan<sup>®</sup> (fluconazole) 150mg tablet is indicated for the treatment of vaginal candidiasis a single oral dose<sup>4</sup>, multiple doses are recommended only in a subset of those affected by VVC. This clinical edit will promote the prudent prescribing of this therapy.

## Setting & Population

- Drug/drug class for review: fluconazole 150mg tablets (Diflucan<sup>®</sup>)
- Age range: all ages
- Gender: males and females



## Approval Criteria

- Therapy will be evaluated for dosing of more than 1 tablet dispensed in the most recent 30 days

Approval Diagnoses				
Condition	Submitted ICD-9 Diagnoses/CPT Procedure Codes	Inferred Drugs	Date Range	Client Approval (Initials)
Recurrent vulvovaginal candidiasis	112.1		> 4 diagnoses in the last 365 days	
Diabetes	250.00		2 years	
		Antidiabetic agents	90 days	
HIV/AIDS	042, 795.71, V08		2 years	
		HIV antivirals	90 days	
Cancer	140 - 208		2 years	
		Antineoplastics	12 months	
Pregnancy	Presence of V22-39 or 640-648*		320 days	
	Absence of V21, V24, V27, 72, 73, 59400-59430, 59510-59525, 59610-59622, 641-676 <sup>†</sup> , 763, 634-639,		320 days	
Other		Immunosuppressive agents	90 days	
		Corticosteroids	90 days	

\*ICD-9 codes between 640-648 pertaining to postpartum/delivery codes will be excluded.

<sup>†</sup> ICD-9 codes between 641-676 only pertaining to delivery status will be included.

## Denial Criteria

- Claims for male patients
- Claims for > 1 tablet per 30 days and no approval diagnoses (documented or inferred).

## Required Documentation

Diagnosis of  
Resistant Candidiasis  
MedWatch form:

✓

Progress notes:




## Disposition of Edit

- **Denial:** Exception 682 "Clinical Edit"

## References

1. Sexually transmitted diseases treatment guidelines 2002. Accessed at <http://www.cdc.gov/std/treatment/default.htm> on May 28, 2003.
2. Hurley R. Recurrent Candida infections. Clin Obstet Gynecol 1981;8:209-13.
3. Haefner HK. Current evaluation and management of vulvovaginitis. Clin Obstet Gynecol 1999;42:184-95.
4. Pfizer, Inc. <http://www.diflucan.com/> Accessed May 28, 2003.

## Client Approval

Please have an authorized representative execute this Clinical Edit criteria verifying receipt by the client and that all elements contained herein are understood.

Client Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

